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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/523,362

02/07/2005

Agnes Chardonnens

13311-00012-US

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07/20/2010

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EXAMINER

KUMAR, VINOD

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

07/20/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/523,362 | <b>Applicant(s)</b><br>CHARDONNENS ET AL. |  |
|                              | <b>Examiner</b><br>VINOD KUMAR       | <b>Art Unit</b><br>1638                   |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5,8-10,13,18,19,29,32,47,49 and 51-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,8-10,13,18,19,29,32,47,49 and 51-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 May 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Objections and Rejections***

1. Claims 1, 5, 8-11, 13, 15, 18-19, 29, 32, 47, 49 and newly added claims 51-54 are pending. Newly added claims 51-54 fall within the scope of the claims currently under examination.
2. Claims 2-4, 6-7, 12, 14, 16-17, 20-28, 30-31, 33-46, 48 and 50 are previously cancelled.
3. Claims 1, 5, 8-11, 13, 15, 18-19, 29, 32, 47, 49 and newly added claims 51-54 are examined on merits in the present Office action.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 103***

5. Claims 1, 5, 8-10, 13, 18-19, 29, 32, 47 and 49 remain, and newly added claims 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lanahan et al. (WIPO, PCT, WO 00/36126, Published 22 June 2000, Applicant's IDS), and further in view of Gan (Biochem. Biophys. Res. Comm., 187:949-955, 1992), Grant et al. (Biochimica et Biophysica Acta, 1490:33-42, 2000) and Samuelson et al. (Plant Physiol., 118:51-58, 1998) for the reasons of record stated in the Office action mailed 1/15/2010.

Applicant traverses the rejection in the paper filed 4/28/2010.

Lanahan et al. teach expressing a heat-stable thioredoxin protein (an oxidoreductase stress related protein). Furthermore, Lanham et al. also teach expressing microbial (includes yeast) heat-stable thioredoxin protein in transgenic plants. See for example, abstract; pages 1-2, 6-7, 11-13, 17, 20-31; examples 1-2; SEQ ID NOs: 1-7.

Gan teach a nucleic acid sequence encoding a yeast thioltransferase (also called glutaredoxin) having 100% identity to instant SEQ ID NO: 4.

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Grant et al. teach that GRX1 and GRX2 (yeast glutaredoxins) are up-regulated by a range of stress conditions including oxidative, heat shock, osmotic (includes salinity) etc (pg 40, 3<sup>rd</sup> paragraph). Grant et al. also teach that yeast glutaredoxins are small heat-stable oxidoreductases which play an important role in protecting a cell exposed to environmental stresses. Environmental stress would include salt, drought including low temperature. Applicant's attention is directed to abstract, pages 33, 34; page 35, figure 1; page 36, figure 2; page 37, figure 3; page 38, figure 4; page 39, figure 5; pages 40-41.

Samuelson et al. teach that yeast genes can be successfully expressed in plants to obtain expected phenotype and/or enzymatic activity associated with the yeast protein. See in particular, pg 51, abstract; pg 54, figures 1 and 2; pg 55, figure; pg 56, figures 4. The reference also cites additional prior art references to assert that expressing yeast genes in a plant tissue produces expected results (see page 51, right column, 3<sup>rd</sup> paragraph).

At the time the invention was made, it would have been prima facie obvious to one of ordinary skill in the art to modify the method of making a transgenic plant as taught by Lanahan et al., to substitute the coding sequence encoding Lanahan et al. heat-stable thioredoxin protein with a recombinant DNA encoding Gan thioredoxin protein to obtain a transgenic plant and transgenic seed expressing Gan recombinant DNA.

It would have been thus obvious and within the scope of an ordinary skill in the art to over-express Gan glutaredoxin protein in any plant including monocot (maize) or dicot (tomato) plants of Lanahan et al. using any plant transformation method including the one taught by Lanahan et al.

Given that Grant et al. teach glutaredoxin protein (same protein as taught by Gan, emphasis added) are implicated in protecting a cell subjected to an environmental stress (oxidative or osmotic or salinity), one of ordinary skill in the art would have been motivated to over-express Gan nucleic acid sequence encoding glutaredoxin protein in any eukaryotic host cell including a plant cell to produce a transgenic

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plant cell which is regenerated into a stress-tolerant transgenic plant with a reasonable expectation of success.

Given, it was well known in the art at the time the instantly claimed invention was made that yeast genes can be overexpressed in a plant to produce an expected phenotype as asserted by Samuelsen et al., it would have been obvious and within the scope of an ordinary skill in the art to obviously try overexpressing Gan's oxidoreductase coding sequence in a plant for the purpose of obtaining environmental (salt, drought etc.) stress tolerant transgenic plant with a reasonable expectation of success.

It would have been obvious and within the scope of an ordinary skill in the art to use Gan nucleic acid sequence encoding the glutaredoxin protein as a DNA marker in any DNA hybridization based technique, such as Southern blot or DNA dot blot analysis to identify stress-tolerant transgenic plant with a reasonable expectation of success.

While one of ordinary skill in the art would have expressed Gan's nucleic acid sequence encoding oxidoreductase protein in a plant using any method of plant transformation including the one taught by Lanahan et al., for the purpose of obtaining a transgenic plant with environmental (salt, drought etc.) stress tolerant characteristics as discussed above, it would have been obvious that said transgenic plant would have also exhibited any other characteristics including increased biomass, photosynthetic yield and/or dry matter production traits that are related to the property of Gan's oxidoreductase protein over-expression in said transgenic plant.

Thus, the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

**Response to Applicant's Arguments:**

Applicant's arguments are not persuasive to suggest that Ritte's declaration filed under 37 CFR § 1.132 should overcome the present rejection under 103(a).

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Applicant is reminded that issue in the present obviousness analysis is whether there was any reason based on prior art teachings that would have motivated one of ordinary skill in the art to try expressing (obvious to try, emphasis added) Gan sequence in a plant to produce an abiotic stress tolerant transgenic plant. The answer to this question is obviously yes. As discussed above, one of ordinary skill in the art would have been obviously motivated to combine the teachings of Lanahan et al., Gan, Grant et al. and Samuelsen et al. to arrive at the claimed invention with a reasonable expectation of success.

Even Ritte's declaration filed under 37 CFR § 1.132 clearly acknowledges that a skilled person might have recognized expression of yeast GRX2 gene in a plant would have increased tolerance to salinity, drought, and/or low temperature (see lines 4-7 of item 17 of the declaration). It is important to note that obviousness does not require an absolute certainty of success but merely a reasonable expectation thereof, so long as the motivation or suggestion to combine the teaching of the cited references is known or disclosed in the prior art and is obvious to one skilled in the art and this is sufficient to establish a *prima facie* case of obviousness. In the instant case, one of ordinary skill in the art would have used teachings of the prior art as discussed above to arrive at the claimed invention with a reasonable expectation of success.

It is further noted that there is no scientific rationale presented either in Applicant's arguments or in Ritte's declaration to suggest that expressing a yeast gene in a transgenic plant environment would have produced unexpected results. None of the references (Exhibits 1-3) cited in Applicant's declaration suggest that expression of yeast GRX protein would have produced unexpected results.

While it is known that yeast and plants are evolutionary divergent organisms, however it was well understood in the prior art that yeast genes can be successfully expressed in plants to obtain expected phenotype and/or enzymatic activity associated with the yeast protein. For example, Samuelsen et al. clearly points us in that direction as discussed above (see in particular, page 51, abstract; page 54, figures

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1 and 2; page 55, figure; page 56, figures 4). Samuelsen et al. even cites additional prior art references to assert that expressing yeast genes in a plant tissue produces expected results (see page 51, right column, 3<sup>rd</sup> paragraph). Given, Grant et al. clearly establishes the function of oxidoreductases (GRX1, GRX2) in abiotic stress response, it would have been obvious to try overexpressing any oxidoreductase, including yeast oxidoreductase of Gan in a plant to arrive at the claimed invention with a reasonable expectation of success. Just to presume that expression of GRX proteins in a plant would have produced unexpected results because yeast and plants are evolutionary divergent organisms is insufficient to overcome the present obviousness analysis, particularly keeping in view that it was well known in the prior art that it was routine to express yeast genes in plants to produce expected phenotype as asserted by Samuelsen et al.

In the absence of providing an experimental evidence to support the argument that yeast GRX protein(s) would not have produced expected results in plants, it is maintained that it would have been obvious and within the scope of an ordinary skill in the art to have arrived at the claimed invention with a reasonable expectation of success as discussed above.

Furthermore, given oxidoreductases (GRX1, GRX2) in yeast were implicated in abiotic stress response, it would have been an important motivation factor to try expressing said oxidoreductases in plants to produce abiotic stress tolerant plants, given the success of obtaining an expected phenotype upon expression of a yeast protein was well known in the art as asserted by Samuelsen et al.

Contrary to Applicant's allegations (response, lines 4-5 of page 7), Ritte's declaration clearly acknowledges that Grant et al. teach GRX1 and GRX2 (yeast glutaredoxins) are up-regulated by a range of stress conditions including oxidative, heat shock, osmotic (includes salinity (see items 10 of declaration)). Furthermore, the issue is not whether GRX1 was upregulated more than GRX2 in response to abiotic stresses (e.g., heat, osmotic stress etc.). Rather the issue is whether GRX1 and GRX2 response

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to abiotic stresses. Grant et al. teachings would have definitely led one of ordinary skill in the art in that direction. Additionally, Applicant's attention is also directed to abstract, pages 33, 34; page 35, figure 1; page 36, figure 2; page 37, figure 3; page 38, figure 4; page 39, figure 5; pages 40-41 of Grant et al. wherein the reference clearly teach that yeast glutaredoxins are small heat-stable oxidoreductases which play an important role in protecting a cell exposed to environmental stresses.

It is further maintained that given Grant et al. teach glutaredoxin protein (same protein as taught by Gan, emphasis added) are implicated in protecting a cell subjected to an environmental stress (oxidative or osmotic or salinity), one of ordinary skill in the art would have been motivated to over-express Gan nucleic acid sequence encoding glutaredoxin protein in any eukaryotic host cell including a plant cell to produce a transgenic plant cell which is regenerated into a stress-tolerant transgenic plant with a reasonable expectation of success.

It is further maintained that it would have been obvious and within the scope of an ordinary skill in the art to use Gan nucleic acid sequence encoding the glutaredoxin protein as a DNA marker in any DNA hybridization based technique, such as Southern blot or DNA dot blot analysis to identify stress-tolerant transgenic plant with a reasonable expectation of success.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would have arrived at the claimed invention with a reasonable expectation of success by combining the teachings of cited art as discussed above.



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It is important to note that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, one of ordinary skill in the art would have arrived at the claimed invention with a reasonable expectation of success by combining the teachings of cited art.

With regard to Applicant's arguments regarding newly added claims 51-54, Applicant is reminded that while one of ordinary skill in the art would have expressed Gan's nucleic acid sequence encoding oxidoreductase protein in a plant using any method of plant transformation including the one taught by Lanahan et al., for the purpose of obtaining a transgenic plant with environmental (salt, drought etc.) stress tolerant characteristics as discussed above, it would have been obvious that said transgenic plant would have also exhibited any other characteristics including increased biomass, photosynthetic yield and/or dry matter production traits that are related to the property of Gan's oxidoreductase protein over-expression in said transgenic plant.

It is noted Applicant has drawn incorrect comparisons between the teachings of Serrano et al. and/or Kasuga et al. (cited by Applicant in the response, see page 9) and present obviousness analysis. The proteins TPS1 taught in Serrano et al., and DREB1A taught in Kasuga et al. are structurally unrelated proteins affecting different metabolic pathways and signal transduction signaling in plants compared to instantly claimed oxidoreductase. More importantly, it is property of Gan's oxidoreductase protein over-expression in a transgenic environment that would have produced any other characteristics besides abiotic stress tolerance. Neither Ritte's declaration nor the Applicant's arguments suggest that overexpression of a yeast oxidoreductase in a plant would have caused unexpected or surprising results.

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In response to Applicant's arguments that Office action mailed 1/25/07 had raised the issue of unpredictability in the art about abiotic stresses, it is noted that Office raised this issue in a separate rejection under 35 USC 112, first paragraph which is currently withdrawn. It is important to note that the recitation "Environmental stress" as recited in the claims under examination for the Office action of 1/25/07 encompassed stresses that were not described in the specification in such a way as to enable any person skilled in the art to which it pertains, with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. For example, an environmental stress reads on pathogenic stress, insect stress etc., and the specification failed to provide guidance on practicing the invention for the full scope of the claims. Given a pathogenic stress and an abiotic stress do not necessarily share same transduction signal pathway, it was obvious to raise the issue of unpredictability for the full scope of "environmental stress" under 112, 1<sup>st</sup> paragraph.

It is therefore, maintained that the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

6. Claims 11 and 15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lanahan et al. (WIPO, PCT, WO 00/36126, Published 22 June 2000, Applicant's IDS), and further in view of Gan (Biochem. Biophys. Res. Comm., 187:949-955, 1992), Grant et al. (Biochimica et Biophysica Acta, 1490:33-42, 2000), Samuelsen et al. (Plant Physiol., 118:51-58, 1998) and Stomp et al. (Plant Physiol., 92:1226-1232, 1990) for the reasons of record stated in the Office action mailed 1/15/2010.

Applicant does not present any argument in the response filed 4/28/2010.

It is therefore, maintained that it would have been thus obvious and within the scope of an ordinary skill in the art to over-express Gan glutaredoxin protein in any plant cell or plant including a gymnosperm plant cell or plant using any plant transformation method including the one taught by Stomp et al. to arrive at the claimed invention with a reasonable expectation of success as discussed above.

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***Conclusions***

7. Claims 1, 5, 8-11, 13, 15, 18-19, 29, 32, 47 and 49 remain, and newly added claims 51-54 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar, Ph.D. whose telephone number is (571)272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vinod Kumar/

Primary Examiner, Art Unit 1638